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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,170	07/01/2003	Vahid C. Saadat	USGI-004 A	5203

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/612,170	Applicant(s) SAADAT ET AL.	
	Examiner Michael G. Mendoza	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 15, 17, 19, 22-25, 28 and 30-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-14, 16, 18, 20, 21, 26, 27 and 29 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/8/04, 6/10/05, 7/25/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species I in the reply filed on 24 June 2005 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 12 recites the limitation "the internal lock" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-9, 11, 16, 18, 20, 21, 26, 27, and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Ewers et al. 6589208.

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7. 1-9, and 11, Ewers et al. teaches an anchor comprising: a sleeve 32 including proximal 27 and distal bushings 30; wherein the sleeve is adapted to be reconfigured from a reduced delivery profile to an expanded deployed profile (fig. 3 & 4); a suture 34 coupled to the distal bushing and extending through the interior of the sleeve; wherein the suture extends through an aperture in the proximal bushing (see figs.); wherein the sleeve is configured so that application of tension on the suture approximates the distal bushing to the proximal bushing (col. 7, lines 55-67); wherein the sleeve is configured so that application of tension on the suture transitions the sleeve from the reduced delivery profile to the expanded deployed profile (col. 7, lines 55-67); wherein the sleeve is braided (see figs.); wherein the sleeve is formed of individual monofilament elements; wherein the monofilament elements are made of polyester, nylon, TEFLON, polypropylene or combinations of these materials (col. 6, lines 39-41); wherein the sleeve comprises a shape memory material; an internal lock for retaining the sleeve in the expanded deployed profile (col. 3, lines 32-51).

8. As to claims 16, 18, 20, 21, 26, 27, and 29, Ewers et al. teaches an anchor comprising: a shank having proximal and distal ends; and a reconfigurable member disposed on the distal end of the shank, the reconfigurable member having a reduced delivery profile and an expanded deployed profile; wherein the reconfigurable member comprises a plurality of struts affixed to the distal end of the shank/fixation point, a suture coupled to the fixation point; the plurality of struts having a reduced delivery profile wherein the plurality of struts are substantially parallel to the shank and an expanded deployed profile wherein the plurality of struts extend at angles away from the

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shank; wherein the shank is arranged so that tension applied to the shank urges the reconfigurable member to the expanded deployed profile; wherein the reconfigurable member comprises a shape memory material; wherein the fixation point comprises a distal bushing and distal end of each on of the plurality of struts is coupled to the distal bushing and the proximal end of each on of the plurality of struts is coupled to a proximal bushing; and wherein in the expanded deployed profile, the plurality of struts bow radially outward to form a disk-like configuration (fig. 6).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewers et al. in view of Gannoe et al. 6746460.

11. Ewers et al. teaches the anchor of claim 1. It should be noted that Ewers et al. fails to teach a coating of bioactive agent applied to an outer surface of the sleeve.

However, Gannoe et al. teaches a device used for gastric reduction having a bioactive agent coating. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a bioactive coating to the device of Ewers et al. to promote healing or protect against infection (col. 5, lines 9-11).

Allowable Subject Matter

12. Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
9/12/55